4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1601]

Custom Device Exemption; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Custom Device Exemption." FDA has developed a draft guidance to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in the Food, Drug, and Cosmetic Act (the FD&C Act). The intent of this guidance is to provide draft definitions of terms used in the custom device exemption, explain how to interpret the "five units per year of a particular device type" language contained in the FD&C Act, describe what information FDA proposes manufacturers should submit in the custom device annual report, and provide recommendations on how to submit an annual report for devices distributed under the custom device exemption. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Custom Device Exemption" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Erin Keith, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1404, Silver Spring, MD 20993-0002, 301-796-6384, CustomDevices@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The custom device exemption is set forth at section 520(b)(2)(B) of the FD&C Act (21 U.S.C. 360j(b)(2)(B)). A custom device is in a narrow category of device that, by virtue of the rarity of the patient's medical condition or physician's special need the device is designed to treat, it would be impractical for the device to comply with premarket review regulations and performance standards.

Effective on July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) implemented changes to the custom device exemption contained in section 520(b) of

the FD&C Act. The new provision amended the existing custom device exemption and introduced new concepts and procedures for custom devices, such as:

- Devices created or modified in order to comply with the order of an individual physician or dentist;
- the potential for multiple units of a device type (limited to no more than five units per year) qualifying for the custom device exemption; and
- annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed under section 520(b) of the FD&C Act.

Under FDASIA, "devices" that qualify for the custom device exemption contained in section 520(b) of the FD&C Act were clarified to include no more than "five units per year of a particular device type" that otherwise meet all the requirements necessary to qualify for the custom device exemption.

The guidance also provides draft definitions of terms used in the custom device exemption, explains how FDA plans to interpret the concept of "five units per year of a particular device type" in section 520(b)(2)(B) of the FD&C Act, describes what information manufacturers should submit in a custom device annual report (annual report) to FDA, and provides guidance on how to submit an annual report for devices distributed under the custom device exemption.

On November 19, 2012, FDA published a Notice of Request for Comments in the Federal Register (77 FR 69488), requesting stakeholders to submit information on and examples of appropriate use of the custom device exemption for assistance in drafting this guidance based on specific questions asked in the Notice. FDA has reviewed all the comments from the Notice and has taken them into consideration for this draft guidance.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the custom device exemption. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. To receive "Custom Device Exemption," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1820 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of Information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of

information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance for Custom Device Exemption

This guidance is intended to assist industry by providing draft definitions of terms used in the custom device exemption, explains how FDA proposes to interpret the "five units per year of a particular device type" language contained in section 520(b)(2)(B) of the FD&C Act, describes what information FDA proposes should be submitted in a custom device annual report, and provides recommendations on how to submit an annual report in preparing for annual reports for devices distributed under the custom device exemption. In addition, manufacturers of custom devices are required to sign and submit a Custom Devices Annual Report Truthful and Accurate certificate with their annual report.

Description of Respondents: The respondents of this collection of information are manufacturers of medical devices deemed to be custom devices subject to FDA’s laws and regulations. The Agency estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Guidance Title: Custom Device Exemption	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Section VI. Annual Reporting	33	1	33	40	1,320

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates it will receive 33 reports for custom devices annually. The Agency reached this estimate by the number of pre-FDASIA manufacturers who qualified for custom devices and that percentage of current manufactures that qualify under post-FDASIA requirements. Only 10 percent of manufacturers would meet this qualification, which was calculated by adding the number of estimated old custom device manufactures with the estimated new manufacturers submitting annual reports of custom devices each year. FDA estimates it will take custom device manufacturers approximately 40 hours to complete the annual report described in section VI of the draft guidance. FDA reached this time estimate based on its expectation of the amount of information that should be included in the report.

Before the proposed information collection provisions contained in this draft guidance become effective, FDA will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it display a currently valid OMB control number.

This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA (44 U.S.C. 3501-3520). The collections of information in 21 CFR 814, subparts B and E have been approved under OMB control number 0910-0231; the collections of information in 21 part

812 have been approved under OMB control number 0910-0078; and the collections of information in 21 part 807, subpart E have been approved under OMB control number 0910-0120.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: January 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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